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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,223	02/28/2006	Norman Godin	BIO0003100104518	7573
34132	7590	01/15/2008	EXAMINER	
COZEN O'CONNOR, P.C.			SNOW, BRUCE EDWARD	
1900 MARKET STREET				
PHILADELPHIA, PA 19103-3508				
			ART UNIT	PAPER NUMBER
			3738	
			MAIL DATE	DELIVERY MODE
			01/15/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/570,223

Applicant(s)

GODIN, NORMAN

Examiner

Bruce E. Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's amendments overcame the previous rejections, however, are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 broadens claim 1 instead of narrowing it; the scope is indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 8, 9, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jayaraman (6,162,245).

Jayaraman teaches:

1. A prosthesis which is fully capable of being implanting in an upper stomach to prevent gastric reflux in an esophagus comprising a tube (see figures 7 and 8) made of a biocompatible polymer that is resistant to gastric acid, the tube having an upper end

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and a lower end, a length, and a constant diameter along the entire length thereof from the upper end to the lower end, the upper end having means for securing (clips 60, 70, 80) to the upper opening of the stomach, the lower end having at least one slit (39, 41) of the tube during a high pressure vomiting event but to facilitate collapsing of the tube under a level of lateral pressure generated by gastric reflux (fully capable of).

Claim 5 and 13, see figure 7.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Note Stinson's 2003/0069646 teachings in the background of the invention and figure 1B.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Godin (5,861,036) in view of Tadaaki (JP3198844) or Godin (5,314,473).

Godin '036 teaches a prosthesis for implanting in an upper stomach to prevent gastric reflux in an esophagus comprising a tube 1 (figure 2) made of a biocompatible polymer (including silicone) that is resistant to gastric acid, the tube having an upper

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end and a lower end, a length, and a constant diameter from the upper end to the lower end, the upper end having means for securing (2 and frictional fit, etc.) to the upper opening of the stomach. However, Godin is silent regarding the lower end having at least one slit. Tadaaki and Godin both teach a similar prosthesis having at least one slit; See figure 7, see element 8 having slits of Tadaaki and figures 11-12, slits 16, of Godin. It would have been obvious to one having ordinary skill in the art to have tried a slit(s) in the prosthesis of Godin '036 as taught by Tadaaki and Godin '473 to allow the prosthesis to invert and/or un-invert easier yielding predictable results. The combination devices are fully capable of inversion of the tube during a high pressure vomiting event but to facilitate collapsing of the tube under a level of lateral pressure generated by gastric reflux.

Regarding claim 9, see clips 8 of Godin '473.

Regarding claim 6, Godin teaches the prosthesis as described above, however, is silent regarding the slits extending 66-95 percent of the length. Figure 12 of Godin teaches the slits extending approximately 50 percent. Figure 3a of Tadaaki shows the claimed range. It would have been obvious to one having ordinary skill in the art to have tried varying lengths of the slits yielding predictable results. Additionally, applicant has not disclosed that this range provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with either range especially in light of claim 5, only claiming about one third the length.

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

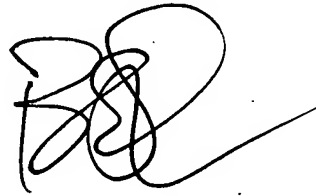
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private-PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bes

A handwritten signature in black ink, appearing to read 'BSN', with a long horizontal line extending to the right.

**BRUCE SNOW**  
**PRIMARY EXAMINER**